

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

PROMOTE INNOVATION LLC,)	
)	
Plaintiff,)	
)	
vs.)	Case No. 1:10-cv-964-TWP-TAB
)	
ROCHE DIAGNOSTICS CORPORATION and)	
ROCHE DIAGNOSTICS OPERATIONS, INC.,)	
)	
Defendants.)	

ENTRY ON MOTION TO DISMISS

This *qui tam* action is before the Court on Defendants Roche Diagnostics Corporation and Roche Diagnostic Operations, Inc.’s (collectively, “Roche”) 12(b)(6) Motion to Dismiss. This dispute stems from David O’Neill’s (“O’Neill”) allegations that Roche has violated 35 U.S.C. § 292(a) by falsely marking diabetes monitoring and testing products with patent numbers of expired or unenforceable patents. Plaintiff Promote Innovation LLC (“Promote”) has since been assigned O’Neill’s interest in the present action. For the reasons set forth below, Roche’s Motion to Dismiss (Dkt. 74) is **GRANTED**.

I. LEGAL STANDARD

When reviewing a 12(b)(6) Motion, the Court takes all well-pleaded allegations in the complaint as true and draws all inferences in favor of the plaintiff. *Bielanski v. County of Kane*, 550 F.3d 632, 633 (7th Cir. 2008) (citations omitted). However, the allegations must “give the defendant fair notice of what the . . . claim is and the grounds upon which it rests” and the “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Pisciotta v. Old Nat’l Bancorp*, 499 F.3d 629, 633 (7th Cir. 2007) (citations omitted). Stated differently, the complaint must include “enough facts to state a claim to relief that is plausible on

its face.” *Hecker v. Deere & Co.*, 556 F.3d 575, 580 (7th Cir. 2009) (citations and internal quotations omitted). To be facially *plausible*, the complaint must allow “the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citation omitted).

II. BACKGROUND

On February 23, 2010, O’Neill filed this *qui tam* action in the U.S. District Court for the Northern District of Illinois. In response to Roche’s motion to dismiss or transfer venue, the Northern District transferred the case to this Court and granted O’Neill leave to file an amended complaint within 14 days. On July 23, 2010, O’Neill filed his First Amended Complaint. On September 7, 2010, Promote filed a motion to substitute as plaintiff and leave to file a second amended complaint. On September 20, 2010, the Court granted Promote’s motion. That same day, Promote filed a Second Amended Complaint, which is the relevant complaint for purposes of the present Motion to Dismiss.

In the Second Amended Complaint, Promote alleges that Roche has engaged in an unlawful campaign of false patent marking on its ACCU-CHEK® products. Three patents are involved: (1) U.S. Patent No. Re. 36,268 (“the ‘268 patent”), (2) U.S. Patent No. 4,891,319 (“the ‘319 patent”), and (3) U.S. Patent No. 4,924,879 (“the ‘879 patent”). First, Promote alleges that Roche falsely marked the ‘268 patent on its ACCU-CHEK® Aviva Diabetes Monitoring Kit, even though the ‘268 patent was declared unenforceable in 2005. Second, Promote alleges that Roche falsely marked the ‘319 patent on its ACCU-CHEK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Aviva Test Strips, and ACCU-CHEK® Comfort Curve Test Strips, even though the ‘319 patent expired in 2007. Third, Promote alleges that Roche falsely marked the ‘879

patent on its ACCU-CHEK® Compact Plus Diabetes Monitoring Kit, ACCU-CHEK® Softclix Plus Lancing Device, ACCU-CHEK® Softclix Lancets, ACCU-CHEK® Aviva Diabetes Monitoring Kit, ACCU-CHEK® Multiclix Lancing Device Kit, and ACCU-CHEK® Multiclix Lancets, even though the '879 patent expired in 2008.

Significantly, this is not the Court's first foray into dealing with the '268 patent. In *Roche Diagnostics Corp. v. Apex Biotechnology Corp.*, No. 1:04-CV-00358 (hereinafter, "*Roche v. Apex*"), the district court judge held a bench trial and issued an opinion ruling that the '268 patent was unenforceable due to inequitable conduct committed by an employee of a company called Tall Oak, whose patents were later purchased by Roche. Nonetheless, the district court did not issue an appealable final judgment because additional claims involving a different patent remained.¹ After further legal wrangling about the other patent, the parties reached a settlement agreement and stipulated to a dismissal of the case with prejudice.² The district court subsequently dismissed the case with prejudice and without entry of a final judgment. Additional facts are added below as needed.

¹More precisely, the Court initially dismissed the case with a judgment, but withdrew the judgment and reopened the case a day later because the bench trial did not dispose of all claims in the lawsuit.

²Despite the procedural posture of this case, the Court believes that, under the circumstances, it is both necessary and appropriate to consider facts found in publicly available records attached by the parties. It is well-settled that the Court may take judicial notice of matters of public record without converting a 12(b)(6) motion into a motion for summary judgment. *Henson v. CSC Credit Services*, 29 F.3d 280, 284 (7th Cir. 1994) (considering public court documents filed in earlier Indiana state case); *see also Wright v. Associated Ins. Cos. Inc.*, 29 F.3d 1244, 1248 (7th Cir. 1994) ("Documents attached to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to his claim.").

III. DISCUSSION

Among other things, Roche develops, manufactures, and sells blood glucose meters and test strips used in the monitoring of diabetes under the ACCU-CHEK® brand name. Promote alleges that certain patent markings on these products violate 35 U.S.C. § 292(a), which provides:

Whoever marks upon, or affixes to, or uses in advertising in connection with any unpatented article, the word “patent” or any word or number importing that the same is patented, for the purpose of deceiving the public . . . [s]hall be fined not more than \$500 for every such offense.³

The two elements of a § 292 false marking claim are: “(1) marking an unpatented article and (2) intent to deceive the public.” *Forest Group, Inc. v. Bon Tool Co.*, 590 F.3d 1295, 1300 (Fed. Cir. 2009) (citation omitted). Roche makes two separate arguments in support of dismissal. First, Promote failed to plead a violation of Section 292 with respect to products marked with the ‘268 patent because such products are not “unpatented articles” as a matter of law. Second, Promote failed to plead sufficient underlying facts to plausibly show that Roche acted with the requisite intent to deceive the public. Each argument is addressed in turn below.

A. Does the use of the ‘268 patent mark amount to marking an “unpatented article”?

With respect to the first element of a Section 292 claim, the Federal Circuit has stated that “in order to determine if an article is ‘unpatented’ for purposes of Section 292 it must be first

³This statute has led to some interesting cases with some jaw-dropping damages calculations. For a high-volume business, a civil fine of \$500 per article can launch damages through the stratosphere. *See Pequignot v. Solo Cup Co.*, 608 F.3d 1356, 1361 (Fed. Cir. 2010) (plaintiff sought roughly \$10,800,000,000,000 (\$10.8 trillion) – half of which would be shared with the United States – in *qui tam* action alleging that patent holder falsely marked its plastic drinking cups after the patents had expired).

determined whether the claims of a patent cover the article in question.” *Clontech Lab., Inc. v. Invitrogen Corp.*, 406 F.3d 1347, 1352 (Fed. Cir. 2005). Promote relies exclusively on *Roche v. Apex*, discussed above, to bolster its contention that the use of the ‘268 patent mark amounts to marking an unpatented article. After all, the district court judge in *Roche v. Apex* unquestionably ruled that the ‘268 patent was unenforceable due to inequitable conduct. Roche counters that because no appealable final judgment was ever issued, the finding of unenforceability is not entitled to preclusive effect under the doctrine of collateral estoppel.

Both sides have case law that ostensibly supports their positions. Promote leans heavily on *Hartley v. Mentor Corp.*, 869 F.2d 1469 (Fed. Cir. 1989), while Roche primarily hangs its hat on *Vardon Golf Co., Inc. v. Karsten Manufacturing Corp.*, 294 F.3d 1330 (Fed. Cir. 2002). A summary of each case is instructive.

In *Hartley* (Promote’s main case), a patent owner (Hartley) and his exclusive licensee (AHS) sued 3M for patent infringement of the ‘274 patent in the United States District Court for the Central District of California. *Hartley*, 869 F.2d at 1471. The court granted summary judgment in favor of 3M, ruling that the ‘274 patent was invalid. *Id.* The parties entered into a settlement agreement, which provided for entry of a stipulated judgment dismissing the infringement claim against 3M with prejudice. *Id.* Right after this litigation ended, Mentor (a third-party) purchased AHS’s rights under AHS’s licensing agreement with Hartley, but refused to pay Hartley royalties in light of the earlier litigation and a provision in the license stating that no royalties were required for U.S. sales should the ‘274 patent be held invalid. *Id.* The record also indicated that AHS had represented to Mentor that no royalties were due on its U.S. sales. *Id.* After Mentor refused to pay royalties, Hartley cancelled the license and sued. *Id.* Mentor

counterclaimed, asserting that the ‘274 patent at the center of the dispute was invalid due to the prior litigation. *Id.* Applying collateral estoppel principles, the district court agreed with Mentor and Hartley appealed. *Id.* at 1470.

The Federal Circuit affirmed, holding that issue preclusion may rest on a stipulated judgment. *Id.* at 1472, 1475. In doing so, the court noted: “Where rulings made after a full and fair opportunity to litigate are firm and consistent with the subsequent settlement agreement by the parties and the judgment actually entered in the case, issue preclusion has been applied as to those issues when raised in a subsequent suit . . .”. *Id.* at 1472. Further, the Federal Circuit rejected a bright-line rule that unappealable issues cannot be given preclusive effect, stating “voluntary relinquishment of one’s right to appeal, where one stands as overall loser, does not fall within that rationale.” *Id.*

In *Vardon* (Roche’s main case), the plaintiff sued the defendant, a fellow golf club manufacturer, for infringing two of its patents: the ‘941 patent and the ‘021 patent. *Vardon*, 294 F.3d at 1332. Subsequently, the United States District Court for the Northern District of Illinois granted partial summary judgment in the defendant’s favor on the ‘941 patent, but denied a motion for summary judgment on the ‘021 patent. *Id.* Prior to bringing the lawsuit, the plaintiff had filed a reissue application for the ‘941 patent and, two months after the court granted summary judgment, a reissue patent (“the ‘950 reissue patent”) was issued. *Id.* Significantly, in order to obtain the reissue, the plaintiff had to surrender the ‘941 patent, thereby extinguishing its right to appeal the court’s decision on summary judgment. *Id.* The plaintiff subsequently filed a second lawsuit against the same defendant in the same district court, this time using the ‘950 reissue patent in lieu of the now-defunct ‘941 patent. *Id.* In this second lawsuit, the defendant

argued that plaintiff was collaterally estopped from making essentially the same arguments as to the '950 reissue patent that had already been rejected as to the '941 patent. *Id.* The district court agreed and the defendant appealed, arguing that the court's prior decision to grant summary judgment should not have been given preclusive effect "because that decision was neither final nor appealable." *Id.* at 1332-33.

The Federal Circuit, applying Seventh Circuit collateral estoppel principles, sided with the defendant, holding that the grant of partial summary judgment in the first lawsuit "was not final for purposes of collateral estoppel." *Id.* at 1333. Therefore, the district court in the second lawsuit "erred when it accorded the decision [in the first lawsuit] preclusive effect." *Id.* In its decision, the Federal Circuit relied heavily on *Miller Brewing Co. v. Joseph Schlitz Brewing Co.*, 605 F.2d 990 (7th Cir. 1979), citing it for the proposition that "to be 'final' for purposes of collateral estoppel the decision need only be immune, as a practical matter, to reversal or amendment. . . [and] the possibility of appeal contributes directly to the determination of finality. . ." *Id.* Neither party moved to certify the court's interlocutory decision as final under Fed. R. Civ. P. 54(b) and, consequently, the defendant never had the opportunity to appeal. *Id.* at 1334. Thus, the decision granting summary judgment "cannot be said to be 'final' for collateral estoppel purposes as that term is defined either by the Seventh Circuit or the Restatement." *Id.* The plaintiff countered that the defendant theoretically could have preserved its ability to appeal by availing itself of certain procedural mechanisms, but the Federal Circuit rejected this argument as "speculative" and "without merit." *Id.* At bottom, the grant of partial summary judgment should not have been considered "final for purposes of collateral estoppel. . ." *Id.* at 1335.

There appears to be some tension in the case law. Nonetheless, this Court believes that

the more recent *Vardon* decision is controlling. Because the *Roche v. Apex* case involved more than the '268 patent and the parties purchased their peace via settlement before the case could be fully adjudicated, Roche never had the right to appeal the district judge's ruling. The decision clearly was not "immune . . . to reversal or amendment." *Id.* at 1334. This fact is significant. Applying Seventh Circuit principles, the *Vardon* court placed great emphasis on the importance of the availability of appellate review:

In *Miller Brewing Co. v. Jos. Schlitz Brewing Co.*, the Seventh Circuit set forth the requirements for finality under the doctrine of collateral estoppel. The court held that in order "[t]o be 'final' for purposes of collateral estoppel the decision need only be immune, as a practical matter, to reversal or amendment." According to the court, the possibility of appeal contributes directly to this determination of finality, which "turns upon such factors as the nature of the decision (i.e., that it was not avowedly tentative), the adequacy of the hearing, and the opportunity for review." In so holding, the Seventh Circuit explicitly adopted the approach followed by the Restatement (Second) of Judgments . . . which states that the fact "that the decision was subject to appeal or was in fact reviewed on appeal [is a] facto[r] supporting the conclusion that the decision is final for the purpose of preclusion."

Id. at 1333-34; *see also Innovad Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1334 (Fed. Cir. 2001)

("A 'full and fair opportunity to litigate' a particular issue includes a party's ability to appeal.").

Moreover, upon closer examination, the Court believes that *Hartley* is factually distinguishable from the present circumstances. In *Hartley*, the district court's summary judgment decision (the one later given preclusive effect) appeared to dispose of *all* claims in the litigation. *See Hartley v. Minn. Mining & Mfg. Co.*, 1983 WL 52339 (C.D. Cal. Nov. 8, 1983). This presumably paved the way for Hartley to appeal soon after the decision; instead, he opted

to relinquish this right by settling.⁴

Additionally, it is true, as Promote highlights, that in *Miller*, 605 F.2d 990, the Seventh Circuit recognized that in some circumstances a non-final judgment can be given preclusive effect. *Id.* at 996 (“‘Finality’ in the sense of 28 U.S.C. § 1291 is not required.”). However, it is significant, as Roche notes, that the non-final judgment that was given preclusive effect in *Miller* was itself a prior determination *by the Seventh Circuit on an interlocutory appeal*. *Id.* at 995-96. Thus, in *Miller*, actual appellate review had been afforded. Under the unique circumstances presented by this case, the Court finds that collateral estoppel would not bar enforcement of the ‘268 patent.

But even if the Court went the other way on the collateral estoppel issue, its decision with respect to the ‘268 patent would still remain intact. The second element of a § 292 false marking claim – “intent to deceive the public” – requires the plaintiff to show “by a preponderance of the evidence that the party accused of false marking *did not have a reasonable belief* that the articles were properly marked (i.e. covered by the patents).” *Clontech*, 406 F.3d at 1352-53 (emphasis added). With respect to the ‘268 patent, the only factual allegation that Roche acted with intent to deceive the public is that it knew about the district court’s prior decision in *Roche v. Apex*. However, because the thorny collateral estoppel issue is a close call, Roche had, at the very least, a “reasonable belief” that the ‘268 patent articles were properly marked. Stated differently, the Court’s decision is reinforced by the fact that this

⁴It is worth noting, however, that the district court’s decision is titled a “Partial Summary Judgment.” Thus, it is somewhat unclear when exactly Hartley’s right to appeal would have been triggered. Nonetheless, even if Hartley could not have appealed immediately, the Court would still side with Roche because *Varcon* is more on-point and applies Seventh Circuit collateral estoppel principles.

was, in the Court's estimation, a very tough decision.

For the reasons set forth above, Promote failed to state a claim upon which relief can be granted with respect to the '268 patent because the use of the '268 patent mark does not amount to a "false patent marking" as a matter of law. Promote can plead no additional facts that could affect the Court's decision on the '268 patent. Accordingly, Promote's claims related to marking the '268 patent are **DISMISSED** with prejudice.

B. Did Promote plead adequate facts showing Roche's "intent to deceive the public"?

Roche also argues that, with respect to the '319 and '879 patent, Promote's Second Amended Complaint fails to allege with particularity that Roche acted with intent to deceive the public. The Court's decision is informed by the Federal Circuit's recent decision in *In re BP Lubricants USA Inc.*, – F.3d –, 2011 WL 873147 (Fed. Cir. March 15, 2011), where the Federal Circuit unequivocally clarified that "Rule 9(b)'s particularity requirement applies to false marking claims and that a complaint alleging false marking is insufficient when it only asserts conclusory allegations that a defendant is a 'sophisticated company' and 'knew or should have known' that the patent expired." *Id.* at *1. Similarly, allegations that the defendant marked its products with expired patent numbers "for the purpose of deceiving the public and its competitors" are unhelpful. *Id.* In other words, a plaintiff cannot scale Rule 9(b)'s gatekeeping function by sprinkling a complaint with magic buzzwords and boilerplate language.

On this point, Rule 9(b) provides, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Further, Rule 9(b) requires identification of the specific "who, what, when, where, and how" of the alleged false statement.

Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 (Fed. Cir. 2009). As the Federal Circuit noted, “Permitting a false marking complaint to proceed without meeting the particularity requirement of Rule 9(b) would sanction discovery and adjudication for claims that do little more than speculate that the defendant engaged in more than negligent action.” *In re BP*, 2011 WL 873147, at *2. Thus, to state an actionable claim under Rule 9(b), a plaintiff must allege “sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.” *Id.* at *3 (quoting *Exergen*, 575 F.3d at 1327). More specifically, “a complaint must in the § 292 context provide some objective indication to reasonably infer that the defendant was aware that the patent expired.” *Id.*

Because Promote’s Second Amended Complaint has provided only generalized allegations rather than specific underlying facts from which the Court can reasonably infer the requisite intent, the Second Amended Complaint has failed to meet the requirements of Rule 9(b) with respect to the ‘319 patent and ‘879 patent. In an attempt to stave off dismissal, Promote specifically points to paragraphs 35, 43-45, 47, 48 and 53 of its Second Amended Complaint. Most of these paragraphs, however, are of the type that were either specifically addressed in *In re BP* and/or are bereft of factual content. Moreover, some of these allegations are made “upon information and belief,” but do not set forth the facts upon which the belief is reasonably based. *See Exergen*, 575 F.3d at 1330.

Paragraph 35 is the only fact-laden paragraph warranting specific discussion. It provides, “Upon information and belief, Quadrant Drug Delivery Limited granted a license to Defendant through a license agreement. Because patent licenses terminate with the expiration of the patent, upon information and belief, the license agreement between Quadrant . . . and

Roche included the date of expiration of the '319 Patent. . .". But this paragraph only invites the Court to engage in speculation based on the existence of a licensing agreement; it in no way establishes intent or knowledge. Based on these facts pled, "it appears just as likely . . . that [defendant] made a marking error" and "inconsistency (to the extent the complaint implies such) does not amount to intent to deceive." *Brinkmeier v. BIC Corp.*, 2010 WL 3360568, at *10 (D. Del. Aug. 25, 2010). In sum, Promote's Second Amended Complaint fails to allege particular facts plausibly suggesting an intent to deceive the public. Accordingly, the Second Amended Complaint fails to state a claim and Roche's 12(b)(6) Motion is **GRANTED**.

C. Should the Second Amended Complaint be dismissed with or without prejudice?

Rule 15(a)(2) admonishes district courts to "freely give leave [to amend the pleadings] when justice so requires." Significantly, the recent *In re BP* decision granted plaintiff leave to amend and recognized that "[o]rdinarily, complaints dismissed under Rule 9(b) are dismissed with leave to amend." *In re BP*, 2011 WL 873147, at *5 (quoting *In re Burlington Coat Factory Sec. Litigation*, 114 F.3d 1410, 1435 (3d Cir. 1997)).

However, the Court is convinced that allowing leave to file a third amended complaint would be futile. *See Airborne Beepers & Video, Inc. v. AT & T Mobility LLC*, 499 F.3d 663, 666 (7th Cir. 2007) (district court did not abuse its discretion in denying plaintiff leave to file fourth amended complaint). Promote and O'Neill, collectively, have been granted leave to amend twice in the face of motions to dismiss. Thus, by the time Promote filed its Second Amended Complaint, it should have been on notice that it needed to cure any weaknesses in its complaint. Moreover, while the *In re BP* case injected some certainty into this area of law, it did not blind side Promote, who argued in the briefing that its Second Amended Complaint satisfied Rule

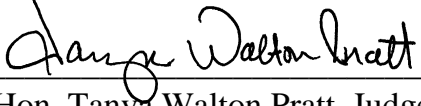
9(b). Finally, and probably most importantly, Promote did not acknowledge, let alone challenge, Roche's argument that the present action should be dismissed with prejudice. The Court cannot help but interpret this conspicuous silence as a tacit acknowledgment that Promote has done all that it can do. For these reasons, Promote's Second Amended Complaint is **DISMISSED** with prejudice.

IV. CONCLUSION

For the reasons set forth above, Roche's Motion to Dismiss (Dkt. 74) is **GRANTED**. Given the Court's decision, Roche's other Motion to Dismiss (Dkt. 106) and Motion to Bifurcate (Dkt. 82) are **DENIED AS MOOT**.

SO ORDERED.

Date: 06/03/2011



Hon. Tanya Walton Pratt, Judge
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